JUN 2 9 2001

510(K) SUMMARY
(as required by 807.92 9c))

K010139

Submitter of 510(K):

KLS-Martin, L.P.
11239-1 St. Johns Industrial Pkwy. S.
Jacksonville, Florida 32246

Phone: 904-641-7746
Fax: 904-641-7378

Contact Person: Jennifer Damato

Date of Summary: December 8, 2000

Trade Name: Zurich Distraction System

Classification Name:

Predicate Device: K992952 – Lorenz Distraction System

Device Description/ Comparison:

The Zurich Distraction System includes several different designs of the implantable distractors intended for bone elongation, which take into account the special conditions of the facial skeleton. The distractors are the same style as the Zurich Ramus Distractor (K983809) and Zurich Maxillary Distractor (K000580) with an assortment of different attachment plates and either fixed or detachable activator arms. The distractors feature a miniaturized design which incorporates a cylindrical shape with a longitudinal gliding track to accommodate the distractor plates. The devices are attached to bone using KLS-Martin titanium screws (K944565). When using these distractors for transport osteogenesis, a mechanical distraction device is attached to the Mandibular Reconstruction Plate (K950045) and further fixed to the bone with attachment plates. A hex driver is used to rotate the activator arm at a rate of 1mm per day achieving callus distraction. After distraction is complete the activator arm can be removed or can stay in place until device removal. Each Distractor is made of TI-6AL-4V Titanium Alloy.

Intended Use:

The Zurich Distraction System includes devices intended as a bone stabilizer and lengthening (and or transport) device when correction of congenital deficiencies or post traumatic defects of the mandible(including ramus, body, alveolar ridge, palate, symphisis), mid-face, and cranial bones require gradual distraction.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

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KLS-Martin L.P.
C/O Mr. Arthur Ward
Regulatory & Marketing Services, Incorporated
3234 Ella Lane
New Port Richey, Florida 34655

Re: K010139
Trade/Device Name: Zurich Distraction System
Regulation Number: 872.4760
Regulatory Class: II
Product Code: MQN
Dated: May 7, 2001
Received: May 15, 2001

Dear Mr. Ward:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements

concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4692. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

Patricia Cucinotta for

Timothy A. Ulatowski
Director
Division of Dental, Infection Control
and General Hospital Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): K010139

Device Name: Zurich Distraction System

Indications For Use:

The Zurich Distraction System includes devices intended as a bone stabilizer and lengthening (and or transport) device when correction of congenital deficiencies or post traumatic defects of the mandible(including ramus, body, alveolar ridge, palate, symphisis), mid-face, and cranial bones require gradual distraction.

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IS NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ OR Over-The-Counter Use _____
(Per 21 CFR 801-109)

(Optional Format 1-2-96)

Susan Runner

(Division Sign-Off)
Division of Dental, Infection Control,
and General Hospital Devices
510(k) Number K010139